DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 2, 2015

Nemera
Ms. Beatrice Grand Demars
Regulatory Compliance Manager
20 Avenue de La Gare
La Verilliere, 38292
FRANCE

Re: K150562
Trade/Device Name: Safe'n'Sound® Staked Passive Delivery System – Plajex® Version
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: February 27, 2015
Received: March 6, 2015

Dear Ms. Grand Demars:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150562

Device Name

Safe'n'Sound® Staked Passive Delivery System – Plajex® version

Indications for Use *(Describe)*

Single use devices that are indicated for use as an accessory with prefilled ISO Standard plastic syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needle sticks. The intended patient population is unrestricted and may include children and adults, for parenteral methods of administration.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

Assigned 510(k) number:	K150562
Company:	Nemera 600 Deerfield Parkway Buffalo Grove, IL 60089 Phone: (800) 537-0178 Fax: (847) 325-3795
Contact:	Beatrice GRAND DEMARS
Date Prepared:	June 1, 2015
Trade/Proprietary Name:	Safe'n'Sound® Staked Passive Delivery System – Plajex® version
Classification Name:	Piston syringe
Classification/Product Code:	21 CFR 880.5860, Class II, Product Code MEG
Predicate Device:	K141664 Safe'n'Sound® Passive Delivery System – Cone version by Nemera

Device Description:

This submission is provided for modifications to the predicate device, which includes design changes and addition of an optional loose extended finger flange. Details are provided in Table 1 hereafter.

The Safe'n'Sound® Staked Passive Delivery System - Plajex® Version is a non-sterile single use anti-needle stick accessory for use with Plajex® sterile prefilled ISO Standard plastic syringes. It fits with Plajex® 1 mL-long staked syringes with a maximum needle length of ½". It consists of a subassembly with a loose plunger rod and an optional loose extended finger flange. The proposed device will be assembled along with the prefilled syringe by the pharmaceutical company. Upon completion of the injection, the needle is then covered by the body protecting the user from potential sharps needle stick injury.

The device is made of molded plastic and have a stainless steel spring.

Intended Use:

Single use devices that are indicated for use as an accessory with prefilled ISO Standard plastic syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needle sticks. The intended patient population is unrestricted and may include children and adults, for parenteral methods of administration.

The subject of this premarket notification is an adjustment of device design in order to make it compatible with ISO Standard plastic syringe, while the legally marketed device is currently compatible with ISO Standard glass syringe. This premarket notification also covers the description of an optional loose extended finger flange. These changes imply slight modification of design but do not impact the fundamental technology of the device.

Technological Characteristic Comparison Summary to Predicate Device:

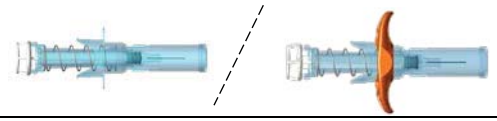
The Safe'n'Sound® Staked Passive Delivery System – Plajex® version is similar to the predicate device in general technological features and principle of operation. Both are molded plastic subassemblies and plunger rod. Both have a spring that activates upon injection completion to fully contain the needle. However, the Cone, Sleeve and Plunger Rod components has been slightly redesigned to fit with Plajex® syringe.

In addition, the Safe'n'Sound® Staked Passive Delivery System – Plajex® version proposes an optional loose Extended Finger Flange (EFF) to increase handle surface. EFF component is made in same material than Plunger Rod with addition of an orange dye.

A side by side comparison is available below in Table 1.

These changes do not raise new questions of safety and effectiveness of the device as proven by design and process validations, bench testing, biocompatibility testing and simulated clinical use studies performed.

Table 1 Side by Side Comparison with the Predicate Device

	New device Safe'n'Sound® Staked Passive Delivery System - Plajex® Version	Predicate device Safe'n'Sound® Staked Passive Delivery System - Cone version	Discussion
			
General technological features and principle of operation	Molded plastic assembly consisting of body, cone, sleeve, plunger rod, EFF (optional) and spring that activates upon injection completion to fully contain the needle	Molded plastic assembly consisting of body, cone, sleeve, plunger rod, and spring that activates upon injection completion to fully contain the needle	Same principle, EFF optional component has been added to the new device to increase finger flange surface.
Material composition			
Body	Polycarbonate (transparent, natural with no colorant)		Same material
Cone	Polycarbonate (transparent, natural with no colorant)		Same material
Sleeve	Polycarbonate (transparent, natural with no colorant)		Same material
Spring	Bright stainless steel		Same material
Plunger rod	Polypropylene with colorant (white masterbatch)		Same material
Extended Finger Flange (EFF)	Polypropylene with colorant (orange masterbatch)	Not applicable	EFF component is made in same material than Plunger Rod with addition of an orange dye**
Mechanical specification			
Specifications	Internal specifications		Same specifications unless 2 items (syringe loading and EFF disassembly) adapted due to the change in the design

** Change has been assessed. Biocompatibility tests conducted (cytotoxicity, irritation and sensitization) demonstrate that Safe'n'Sound® Plajex® version including EFF is biocompatible regarding these 3 requirements – see Section 15. Design Verification testing, bench testing and simulated clinical use study conducted demonstrate that the device performs as intended and the change does not impact the safety or effectiveness of the Safe'n'Sound® Plajex® version

Performance Testing:

Performance has being tested on the Safe'n'Sound® Staked Passive Delivery System – Plajex® version following ISO 23908:2011. Bench testing has been performed following ISO7886-4 and ISO 8537 standards. It confirmed the product functions as intended and is substantially equivalent to the predicate device. Biocompatibility testing performed demonstrates that the product meets ISO 10993-5 and ISO 10993-10 requirements.

Simulated Clinical Testing:

Simulated clinical use testing has been performed. It confirmed that the Safe'n'Sound® Staked Passive Delivery System – Plajex® version could be used to shield needles inside the protection device after use. The study follows Guidance for Industry and FDA Staff for Medical Devices with Sharps Injury Prevention Features dated August 9, 2005 and ISO 23908:2011 standard. It demonstrates that the device is as safe, as effective, and performs as well as the predicate device.

Conclusion:

Based upon the design, technology, performance, functional testing, and intended use, the Safe'n'Sound® Staked Passive Delivery System – Plajex® version is substantially equivalent to predicate device currently marketed under the Federal Food, Drug and Cosmetic Act. Tests performed demonstrates that Safe'n'Sound® Staked Passive Delivery System – Plajex® version is as safe and as effective as the predicate device.